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REDACTED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs and Counterclaim-Defendants, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants and Counterclaim-Plaintiffs.	:	Civil Action No. 3:10-CV-01723-JAP-TJB **PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE THE INTRODUCTION OF EVIDENCE OF THE AVERAGE PARTICLE DIAMETER OF FINE GRANULES IN DEFENDANTS' EXHIBIT BATCH TABLETS** [redacted] **CONTAINS HIGHLY CONFIDENTIAL MATERIAL – FILE UNDER SEAL**

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Pursuant to the Court's motion *in limine* briefing schedule, Plaintiffs submit its opposition to Defendants' Motion *In Limine* To Preclude The Introduction Of Evidence Of The Average Particle Diameter Of Fine Granules In Defendants' Exhibit Batch Tablets [redacted] (D.I. 295) ("Motion").

PRELIMINARY STATEMENT

Zydus seeks to exclude Plaintiffs' infringement evidence relating to average particle diameter measurements of Zydus' ANDA product [redacted] ("Plaintiffs' APD Evidence"). In support of its Motion, Zydus makes two main arguments – one based on new claim constructions and a second that requires this Court to weigh Plaintiffs' infringement evidence before trial. Neither argument is appropriate at this phase.

First, Zydus yet again attempts to reopen claim construction of the particle size limitations in the asserted claims of the Takeda patents[1]. The Court previously construed each of the particle size limitations for the "fine granules" of the Takeda patents to include a ±10% deviation. (*See* D.I. 113 at 7, 9,10[2]).[3] The Court's constructions do not limit the average particle diameter measurement and the ±10% deviation [redacted] Nevertheless, Zydus advances new claim constructions with these limitations. (*See* D.I. 295 at 6-18). Thus, Zydus' new, litigation-driven claim constructions are specifically tailored to carve out Plaintiffs' infringement [redacted]

[1] The Takeda patents consist of U.S. Pat. Nos. 6,328,994 ("the '994 patent") (Ex. 1); 7,431,942 ("the '942 patent") (Ex. 2); and 7,875,292 ("the '292 patent") (Ex. 3) (collectively "the Takeda patents"). References to exhibits herein refer to exhibits attached to the Declaration of Arlene L. Chow.

[2] By stipulation of the parties and the Court's approval, the Court's *Markman* Order regarding the '994 and '942 patents were binding on the '292 patent; thus, the ±10% deviation also applies to the relevant terms in the '292 patent. (*See* D.I. 97).

[3] For example, the Court construed "fine granules having an average particle diameter of 400 µm or less," which appears in claim 1 of the '994 patent, to mean "fine granules up to and including the enteric coating layer having an average particle diameter of 400 µm (±10%) or less." (*See* D.I. 113 at 7).

[redacted]

Notably, Zydus' new claim constructions conflict not only the Court's claim constructions but also the teachings of the Takeda patents. [redacted] As Takeda stressed at the *Markman* hearing, the Takeda patents disclose that average particle diameter "can be measured by, for example, a laser diffraction particle distribution measurement method" (emphasis added). (*See* the '994 patent at col. 5, ll. 46-47) (Ex. 1).[4]

[redacted]

[4] *See e.g.*, D.I. 295 at 7 (portion of *Markman* hearing transcript excerpted by Zydus, "…the patent states that average particle diameter can be measured by, for example, a laser diffraction measurement method") (emphasis added).
[5] *See e.g.*, Bugay 9/14/2012 Dep. Tr. at 190:8-11 ([redacted]) (Ex. 4).
[6] *See e.g.*, Brittain 9/18/2012 Dep. Tr. at 156:23 to 157:6 ([redacted]) (Ex. 5).
[7] *See e.g.*, Brittain 2/22/2013 Dep. Tr. at 22:9-21; 31:5-21; 33:20 to 34:13 ([redacted]) (Ex. 6).

[redacted][8]

Second, Zydus asks the Court to weigh the evidence and exclude Plaintiffs' infringement testing [redacted] Zydus' ANDA product based on conflicting testimony of the parties' experts. (*See* D.I. 295 at 18-23). But the purpose of a motion *in limine* is to determine whether evidence should be excluded altogether because of some evidentiary failing, not to argue the weight of the evidence. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 275 (D.N.J. 2006). Weighing the evidence is more "appropriately addressed in cross examination [at trial] rather than in a motion in limine to preclude the evidence altogether." *Id.* For that reason alone, Zydus' argument should be rejected.

[redacted]

[8] *See e.g.*, testimony by Zydus' expert, Brittain 9/18/2012 Dep. Tr. at 58:15 to 59:25; 75:8-20; 76:2 to 77:5 (t[redacted] (Ex. 5); *see e.g.*, testimony by Takeda's expert, Bugay 9/14/2012 Dep. Tr. at 174:10 to 175:11 ([redacted]) (Ex. 4)

[9] *See* U.S. Pharmacopeia ("USP") <429> at 1 [redacted] *see also* testimony of Zydus' expert, Brittain 9/18/2012 Dep. Tr. at 18:20-25 ([redacted] (Ex. 5); *see also* Takeda's expert Bugay Amended Supplemental Expert Report dated 1/25/2013 at ¶33 (Ex. 8).

[redacted][12].

Zydus' Motion should be denied *in toto*. Zydus advances new claim constructions nearly one and a half years after this Court's *Markman* Order (*see* D.I. 113) and, contrary to the purpose of a motion *in limine*, Zydus asks the Court to weigh Plaintiffs' APD Evidence based on contradictory testimony of the parties' experts.

ARGUMENT

I. Plaintiffs Properly [redacted]

Zydus' attempt to reopen claim construction is untimely and improper. The Court already considered the parties' claim construction arguments during the claim construction briefing period, the *Markman* hearing, and in Zydus' motion for reconsideration. Nevertheless, Zydus advances new claim constructions further limiting the average particle diameter measurement and 10% deviation [redacted](*See* D.I. 295 at 11). Not only are Zydus' new claim constructions inconsistent with the Court's claim constructions and the teachings of the Takeda patents, [redacted]

[10] *See e.g.*, Meyer-Stout 9/12/2012 Dep. Tr. at 79:10-15 ([redacted]) (Ex. 9).

[11] *See* USP <429> at 1 [redacted]

[12] *See e.g.*, testimony of Zydus' expert Brittain 2/22/2013 Dep. Tr. at 178:24 to 179:2 ([redacted]) (Ex. 6).

[redacted]

A. *Zydus' new claim construction further limiting the average particle diameter measurement and 10% deviation* [redacted] *is inconsistent with the Court's claim construction and the teachings of the Takeda patents*

As the Court is aware, the asserted claims of the Takeda patents include a size limitation of the "fine granules." For each of these terms, the Court incorporated a ±10% deviation to the average particle diameter measurement. (*See* D.I. 113 at 7, 9, 10[13]).[14] Clearly, none of the Court's constructions limit the measurement of the "fine granules" or the ±10% deviation [redacted] In addition, none of the Court's constructions limit the ±10% deviation of the "fine granules" [redacted][15].

It is worth noting that if Zydus wanted average particle size measurements and the 10% deviation [redacted] it could have advanced a claim construction reflecting that. Zydus did not because it could not. The Takeda patents unambiguously teach [redacted]

[13] By stipulation of the parties and the Court's approval, the Court's *Markman* Order regarding the '994 and '942 patents were binding on the '292 patent; thus, the ±10% deviation also applies to the relevant terms in the '292 patent. (*See* D.I. 97).

[14] For example, the Court construed "fine granules having an average particle diameter of 400 µm or less," which appears in claim 1 of the '994 patent, to mean "fine granules up to and including the enteric coating layer having an average particle diameter of 400 µm (±10%) or less." (*See* D.I. 113 at 7).

[15] Zydus even acknowledges that the Court already considered this argument – which Zydus pled during the *Markman* hearing – in rendering its claim construction opinion. (*See* D.I. 295 at 11-12). Nevertheless, Zydus seeks to revisit claim construction and re-argue this point.

[16] *See e.g.*, D.I. 295 at 7 (portion of *Markman* hearing transcript excerpted by Zydus, "…the patent states that average particle diameter can be measured by, for example, a laser diffraction measurement method") (emphasis added); D.I. 70 at 6 (quoting directly from the '994 patent specification at col. 5, ll. 46-47: "The '994 patent teaches that 'average particle diameter…can be measured by, for example, a laser diffraction particle distribution measurement method"

[redacted] (*See* the '994 patent at col. 5, ll. 46-47 (average particle diameter "can be measured by, for example, a laser diffraction particle distribution measurement method") (emphasis added) (Ex. 1)). [redacted] (*See* Meyer-Stout 9/12/2012 Dep. Tr. at 188:24 to 189:13) (Ex. 9).

[redacted] During the *Markman* hearing, Plaintiffs noted the pharmaceutical industry's adoption of ±10% deviation in particle size measurements, as reflected in the USP laser diffraction standard[17]. In that way, Takeda stressed that the 10% reflects a widely-accepted deviation for average particle size measurements. [redacted][18]

In short, the Takeda patents and the Court's claim construction permit [redacted] Zydus' ANDA product to make average particle diameter measurements including the ±10% deviation pursuant to the Court's construction.

(emphasis added); *see also* Plaintiffs' *Markman* Hearing Presentation at Slide 11 (highlighting relevant portion of the '994 specification in yellow, including the specification's teaching that "[a]verage particle diameter…can be measured by, for example, a laser diffraction particle distribution measurement method") (emphasis added) (Ex. 10).

[17] *See* 5/26/2011 *Markman* Hearing Tr. at 19:2-14 (showing PQRI's adoption of the USP standard of error of 10%) (Ex. 11); *see also* Plaintiffs' *Markman* Hearing Presentation at Slide 13 (Ex. 10).

[18] *See* Bugay 9/14/2012 Dep. Tr. at 190:8-11 ([redacted]) (Ex. 4); *see also* Byrn 2/20/2013 Dep. Tr. at 49:24 to 50:10 ([redacted]) (Ex. 12).

B. *Zydus' new claim construction further limiting the average particle diameter measurement and the ±10% variation*

[19] *See* testimony of Zydus' experts, *e.g.*, Brittain 9/18/2012 Dep. Tr. at 14:5-12 ( ) (Ex. 5); *see also* Meyer-Stout 9/12/2012 Dep. Tr. at 113:14-16 (a) (Ex. 9).

[20] *See e.g.*, opinions of Takeda's expert, *e.g.*, Bugay Amended Supplemental Expert Report dated 1/25/2013 at ¶21 ( ) (Ex. 8).

[21] *See* Bugay 9/14/2012 Dep. Tr. at 190:8-11 ( ) (Ex. 4); *see also* Bugay 2/15/2013 Dep. Tr. at 99:25 to 100:3 ( ) (Ex. 13); *see also* Byrn 1/11/2011 Dep. Tr. at 58:9 to 59:4 ( ) (Ex. 14); *see also* Byrn 2/20/2013 Dep. Tr. at 49:24 to 50:10 ( ) (Ex. 12).

[22] *See* D.I. 295 at 16. *Id.*

[23] *See* Brittain 2/22/2013 Dep. Tr. at 22:9-21; 31:5-21; 33:20 to 34:13 ( ) (Ex. 6).

[24] *See* Brittain 9/18/2012 Dep. Tr. at 156:23 to 157:6 ( ) (Ex. 5); *see*

[redacted] (*See* Brittain 2/22/2013 Dep. Tr. at 34:16-24; 38:8-13 (Ex. 6)).

In sum, there is no basis for Zydus' new claim construction given [redacted] for measuring particle size.

C. *Zydus' new claim construction further limiting the ±10% variation* [redacted]

[redacted]

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also Brittain 2/22/2013 Dep. Tr. at 23:3-13 ([redacted]) (Ex. 6).

[redacted]

[25] *See* Bugay 9/14/2012 Dep. Tr. at 166:16 to 167:22 ([redacted] (Ex. 4); *see also id.* at 174:10 to 175:11 ([redacted]) (Ex. 4).
[26] *See* Bugay 9/14/2012 Dep. Tr. at 167:2-13 ([redacted] (Ex. 4).
[27] *See* Byrn 2/20/2013 Dep. Tr. at 214:18-21 ([redacted]) (Ex. 12).
[28] *See* Byrn 2/20/2013 Dep. Tr. at 51:12 to 52:5 ([redacted]) (Ex. 12); *see also id.* at 214:18-21 ([redacted]) (Ex. 12).
[29] *See* Brittain 9/18/2012 Dep. Tr. at 58:15 to 59:25; 75:8-20; 76:2 to 77:5 ([redacted]) (Ex. 5).

[redacted]

Zydus misrepresents the testimony of Plaintiffs' expert and counsel and stresses purported inconsistencies where there are none. (*See* D.I. 295 at 17-18). At the *Markman* hearing, Plaintiffs articulated that according to the USP, "laser diffraction incorporates a plus or minus ten percent standard of error and that takes into account, your Honor, the accuracy of instruments that measure laser diffraction" (emphasis added). (*See* 5/26/2011 *Markman* Hearing Tr. at p. 50:12-16 (Ex. 11)). Plaintiffs never represented that the 10% deviation is limited solely to instrumental error; given the uniformity of both side's experts that instrumental error is just one component of the 10% deviation, it would make no sense for Plaintiffs to do so. In fact, in opposing a 10% deviation, Zydus advanced a 3% instrumental error which the Court rejected, including on reconsideration. (*See*, e.g.,D.I. 116 at 14; D.I. 130)[31]. Because instrument error is just one component of the 10% variation, the 10% variation reflects – but is not limited to -- the "level of accuracy of those instruments." (*See* 5/26/2011 *Markman* Hearing Tr. at p. 50:19-23 (Ex. 11)).

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[30] [redacted] (*See* D.I. 295 at 13-14); *see also* Bugay 9/14/2012 Dep. Tr. at 204:24 to 205:5; 205:15-21 (Ex. 4). Simply, variability in an unknown sample and inaccuracy of a known standard are two separate entities.

[31] Zydus argued that the variation in the average particle diameter measurement should be limited to 3%, not 10%. (*See* D.I. 116 at 14). The section of the USP that Zydus relied on for the 3% figure addressed "confirm[ing] the correct operation of the instrument," which is instrumental error. (*See* D.I. 117 at 9).

[redacted] Given that Zydus' Motion is based on new claim constructions, this Court should reject that Motion on this basis alone.

II. Plaintiffs Properly [redacted]

A. [redacted] *is an issue for trial*

Zydus also asks the Court to weigh conflicting evidence between the parties' experts [redacted] (*See* D.I. 295 at 20). That is improper for a motion *in limine*. The purpose of a motion *in limine* is to decide the admissibility of evidence,

not to argue the weight of the evidence. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 275 (D.N.J. 2006). Weighing the evidence is more "appropriately addressed in cross examination [at trial] rather than in a motion in limine to preclude the evidence altogether." *Id.* For this reason alone, this argument should be rejected and Plaintiffs' APD Evidence should be allowed.

B. [redacted] *and consistent with the claims and teachings of the Takeda patents*

[redacted] (*See* Brittain 2/22/2013 Dep. Tr. at 38:8-13 (Ex. 6)). [redacted]

[32] *See* the '994 patent at col. 15, l.26 to col. 16, l. 27 (Ex. 1); *see also* the '942 patent, at col. 15, l. 10 to col. 16, l. 3 (Ex. 2); *see also* the '292 patent, at col. 15, l. 16 – col. 16, l. 10 (Ex. 3).
[33] *See* Bugay Amended Supplemental Expert Report dated 1/25/2013 at ¶18-19 (Ex. 8); *see also* Byrn 2/20/2013 Dep. Tr. at 96:11-14; 96:23 to 97:2 ([redacted]) (Ex. 12).
[34] *See* Bugay Expert Report dated 1/17/2012 at ¶55 (Ex. 15).

[redacted]

In any event, [redacted][39]. (*See* Bugay 2/15/2013 Dep. Tr. at 137:12-13 ([redacted]) (Ex. 13); *see also* Bugay 9/14/12 Dep. Tr. 196:9-25 ([redacted]

[35] *See* U.S. Pharmacopeia ("USP") <429> at 1 [redacted]; *see also* testimony of Zydus' expert, Brittain 9/18/2012 Dep. Tr. at 18:20-25 ([redacted]) (Ex. 5); *see also* testimony of Zydus' expert Meyer-Stout 9/12/2012 Dep. Tr. at 79:10-15 ([redacted]) (Ex. 9); *see also* Takeda's expert Bugay Expert Report dated 1/17/2012 at ¶70 (Ex. 15); *see also* Takeda's expert Bugay Amended Supplemental Expert Report dated 1/25/2013 at ¶33 (Ex. 8); *see also* Takeda's expert Byrn Rebuttal Expert Report dated 8/31/2012 at ¶63 (Ex. 16).

[36] *See* testimony of Zydus' experts, *e.g.*, Brittain 9/18/2012 Dep. Tr. at 14:5-12 ([redacted]) (Ex. 5); *see also* Meyer-Stout 9/12/2012 Dep. Tr. at 113:14-16 ([redacted] (Ex. 9).

[37] *See* opinions of Takeda's expert, *e.g.*, Bugay Amended Supplemental Expert Report dated 1/25/2013 at ¶21 ([redacted] (Ex. 8).

[38] [redacted] *See* USP <429> at 1 [redacted]

[39] [redacted] *See* ISO standard for Laser diffraction methods (1999) at pp. iv-v ([redacted]

[redacted]

Stated simply, Zydus has failed to show how [redacted] is inadmissible. If anything, Zydus' Motion makes clear that this is a disputed issue appropriate for trial. Nevertheless, Plaintiffs have proffered numerous, valid reasons why [redacted] Thus, the Court should reject Zydus' argument and allow Plaintiffs' properly obtained evidence. Zydus is free to argue at trial that [redacted] is not

[40] [redacted] *See* Bugay 2/15/2013 Dep. Tr. at 136:23-25 (Ex. 13). [redacted]

[41] *See* Bugay 2/15/2013 Dep. Tr. at 137:14-15 ([redacted]) (Ex. 13); *see also* Brittain 2/22/2013 Dep. Tr. at 178:24 to 179:2 ([redacted]) (Ex. 6).

[42] *See* Bugay Expert Report dated 1/17/2012 at ¶70 ([redacted](*citing* ISO standard for Laser diffraction methods (1999) (Ex. 17)) (Ex. 15); *see also* Brittain 2/22/2013 Dep. Tr. at 112:7-22 ([redacted] (Ex. 6).

[43] *See* Brittain 2/22/2013 Dep. Tr. at 110:13-20 (Ex. 6).

warranted, and Plaintiffs will argue the opposite. But that is a matter of proof, not a motion *in limine*.

CONCLUSION

For the reasons stated above, Zydus has failed to show that excluding Plaintiffs' APD Evidence is warranted. Accordingly, Plaintiffs respectfully submit that the Court deny Zydus' [redacted]MIL *in toto*.

Respectfully submitted,

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